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Guidance for the Reregistration of Pesticide Products Containing Methiocarb as the Active Ingredient

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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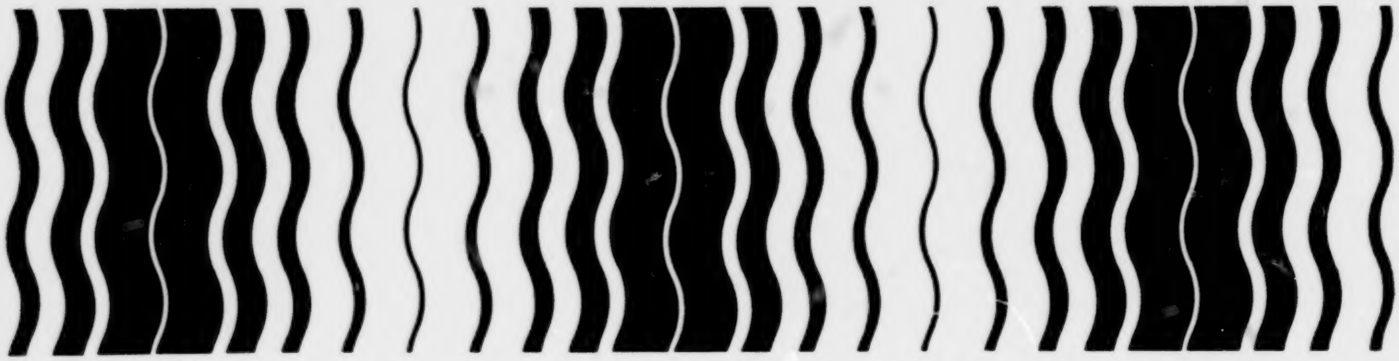

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

METHIOCARB
(100501)

AS THE ACTIVE INGREDIENT

Case Number 577

CAS 2032-65-7

March, 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

TABLE OF CONTENTS

Page

I. Introduction 1

II. Chemical(s) Covered by this Standard 4
  A. Description of Chemical
  B. Use Profile

III. Agency Assessment 6
  A. Science Findings
  B. Summary of Data Gaps
  C. Tolerance Reassessment

IV. Regulatory Position and Rationale. 18
  A. Regulatory Positions
  B. Criteria for Registration
  C. Acceptable Ranges and Limits
  D. Required Labeling

V. Products Subject to this Standard 28

VI. Requirement for Submission of Generic Data 30
  A. What are generic data?
  B. Who must submit generic data?
  C. What generic data must be submitted?
  D. How to comply with DCI requirements
  E. Procedures for requesting a change in protocol
  F. Procedures for requesting extensions of time
  G. Existing stocks provisions upon suspension or cancellation

VII. Requirement for Submission of Product-Specific Data . . 36

VIII. Requirement for Submission of Revised Labeling 37

IX. Instructions for Submission. 37
  A. Manufacturing use products (sole active)
  B. Manufacturing use products (multiple active)
  C. End use products
  D. Intrastate products
  E. Addresses

APPENDICES

I. DATA APPENDICES
  Guide to Tables
  Table A
  Table B
  Table C

II. LABELING APPENDICES
  Summary of label requirements and table
  40 CFR 162.10 Labeling Requirements
  Physical/Chemical Hazards Labeling Statements
  Storage Instructions
  Pesticide Disposal Instructions
  Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES
  Guide to Bibliography
  Bibliography

V. FORMS APPENDICES
EPA Form 8580-1 FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4 Product Specific Data Report
EPA Form 8570-27 Formulator's Exemption Statement

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

Common Name: Methiocarb
Chemical Name: 4-Methylthio-3,5-xylylmethylcarbamate
Chemical Class: Carbamate
CAS Number: 2032-65-7
OPP (Shaughessy) Number: 100501
Empirical Formula: $C_{11}H_{15}NO_2S$
Trade Names: Mercaptodimethur, Metmercapturon, Mesurol, Methiocarbe, Draza, Bay 37344, and H-321
Other Chemical Names: 3,5-dimethyl-4-(methylthio)phenylmethylcarbamate; and 4-(methylthio)-3,5-xylylmethylcarbamate
Physical Characteristics of Technical (T) 3125-258 and pure methiocarb (P):

Color: White (P,T)
Physical State: Crystalline solid (P,T)
Melting Point: 119 °C (P); 121 °C(T)
Boiling Point: Not distillable
Bulk Density: 35-40 lb/cu ft (T)
Solubility: In g/L solvent at 20 °C:
water: 3×10^{-2} (P)
n-hexane: 2 (P)
dichloromethane: > 200 (P)
2-propanol: 80 (P)
toluene: 70 (P)
In mg/L
water: 27 (P)
Vapor pressure: at 60 °C: 1.5×10^{-4} mbar (P)
at 20 °C: 3.8×10^{-7} mbar (T)
at 25 °C: 8.8×10^{-7} mbar (T)
Octanol/water partition coefficient: 2200 at 20 C (P)
pH - not soluble enough (T)
Stability - half life at 22 °C:
pH 4: > 1 year (P)
pH 7: < 35 days (P)
pH 9: 6 hours (P)

B. USE PROFILE

Methiocarb is a systemic carbamate registered for a variety of agricultural and nonagricultural outdoor uses and for use in greenhouses. A versatile pesticide, it is registered as a bird and rodent repellent as well as an insecticide, acaricide and molluscicide. It is used mainly as a bird repellent in corn fields and fruit orchards, and for slug and snail control around ornamental plants.

Additional use sites include blueberries, ginseng, cherries, citrus fruits, avocados, peppers (as a seed crop), sunflowers (as a seed crop), nonbearing deciduous fruit trees, shade trees, ornamental turf, and as a preplant application for unspecified agricultural crops.

The registered types of application include soil, foliar, aerial, and broadcast. Registered formulation types include dust, granular, wettable powder and pelleted/tableted. The wettable powder formulations contain 75% methiocarb while the dust formulations range from 18.75 to 50%, and the granular and pelleted/tableted range from 1 to 2%.

There are currently two registered manufacturing use (MP) products containing methiocarb as a single active ingredient. One, a technical grade, contains 99%, the other a formulation intermediate, contains 75%. A total of 30 end-use (EP) products containing methiocarb are registered under section 3 of FIFRA; 29 contain methiocarb as a single active ingredient and one contains methiocarb in combination with another active ingredient (metaldehyde). There are a total of 65 section 24(c) registrations with 64 containing methiocarb as a single active ingredient and one containing methiocarb in combination with another active ingredient (metaldehyde). There are five intrastate products, all containing methiocarb as a single active ingredient.

III. AGENCY ASSESSMENT

A. SCIENCE FINDINGS

1. Toxicology

The following is a summary of scientific findings based on the available toxicology data on methiocarb.

Acute Effects

Technical methiocarb is highly acutely toxic by the oral route (Toxicity Category I) and of relatively low acute toxicity by the dermal route (Toxicity Category III). Available data are not adequate to assess acute inhalation toxicity and are required. Methiocarb's primary mechanism of toxicity is cholinesterase inhibition and animal studies have shown that the chemical inhibits plasma, erythrocyte, and brain cholinesterase activity.

Chronic Toxicity and Oncogenicity Studies

In a two year feeding/oncogenicity study, 60 male and 60 female rats were treated with 0, 67, 200 or 600 ppm of methiocarb in the diet. The effects of methiocarb administration in this study were judged to be related to cholinesterase inhibition. The no-observable effect level (NOEL) was determined to be 67 ppm (3.35 mg/kg/day). Methiocarb was not oncogenic under the conditions of this study. A second oncogenicity study (mouse) is needed to evaluate the oncogenic potential of methiocarb. In a dog chronic feeding study, effects which appeared to be treatment-related included sporadic incidences of hind limb weakness and tremor in the high dose group (240 ppm) and plasma cholinesterase inhibition of 30 percent or greater at dose levels of 15 ppm and above. The NOEL was determined to be 5 ppm (0.125 mg/kg/day), based on plasma cholinesterase inhibition.

Reproduction

The available rat reproduction study is not adequate to assess reproductive toxicity potential. A new study is required.

Developmental Effects

Two acceptable developmental toxicity studies are available to the Agency:

In a rat study, doses of 1, 3 and 10 mg/kg of methiocarb were administered orally during days 6 through 15 of gestation. although the high dose group showed evidence of weight loss, no indication of developmental toxicity was noted. In this study, the NOEL for maternal effects was 10 mg/kg, and the NOEL for developmental effects was >10 mg/kg.

In a rabbit study, the same dosages were administered on days 6 through 18 of gestation. Again, weight loss was noted in the high dose group, but there was no evidence of developmental toxicity. The NOEL for maternal effects in this study was 3 mg/kg, and the NOEL for developmental effects was >10 mg/kg. No additional data are required.

Mutagenicity

The available mutagenicity studies which consisted of the following: Salmonella reverse mutation test; a mouse micronucleus test; a mouse dominant lethal test; and an *E. coli* DNA damage test are not acceptable and new studies are required. Deficiencies found in these studies included lack of a positive control (mouse dominant lethal); use of an inappropriate positive control and failure to demonstrate that the metabolic enzyme preparations were active (*E. coli* DNA damage); data from non-activated assays were not reported (Salmonella reverse mutation); and micronuclei may not have been detected with the single sampling time employed (mouse micronucleus).

Metabolism

An assessment of the metabolism of methiocarb cannot be made at this time since the available metabolism data are insufficient. In a rat metabolism study a number of metabolites were reported that were not clearly identified. Only one dose level was tested and an insufficient number of animals was used. A new metabolism study is required.

Metabolites

Methiocarb sulfoxide, a metabolite of methiocarb, is also a cholinesterase inhibitor and in some studies has been found to be more acutely toxic than the parent compound. The acute oral toxicity of methiocarb sulfoxide in rats was reported to be 9 mg/kg (males) and 7 mg/kg (females). A 30-day dog feeding study conducted with methiocarb sulfoxide is required to assess potential acute toxicological effects from dietary exposure to residues of methiocarb sulfoxide in/on methiocarb-treated commodities. The acute oral toxicities of other potential metabolites of methiocarb (N-hydroxymethyl methiocarb; N-hydroxymethyl methiocarb sulfone; and N-hydroxymethyl methiocarb sulfoxide) were all found to be less than that of methiocarb.

The following summarizes results of acceptable studies conducted with methiocarb:

Acute oral toxicity (rat)	14-30 mg/kg
Acute dermal toxicity (rabbits)	> 2000 mg/kg
Acute delayed neurotoxicity (hen)	Negative at 380 mg/kg (highest dose tested)

Chronic feeding (rat)	NOEL for cholinesterase inhibition = 67 ppm (3.35 mg/kg/day)
Chronic feeding (dog)	NOEL for cholinesterase inhibition = 5 ppm (0.125 mg/kg/day)
Oncogenicity (rat)	Not oncogenic up to 600 ppm (highest dose tested)
Teratology (rat)	Negative up to 10 mg/kg (highest dose tested)
Teratology (rabbit)	Negative up to 10 mg/kg (highest dose tested)

The following summarizes results of studies conducted with some of methiocarb's purported metabolites.

Acute oral toxicity (rat)

Methiocarb sulfoxide	7-9 mg/kg
N-hydroxymethyl methiocarb	> 112.0 mg/kg
N-hydroxymethyl methiocarb sulfone	> 112.0 mg/kg
N-hydroxymethyl methiocarb sulfoxide	> 160.0 mg/kg

2. Ecological Effects

The following is a summary of scientific findings based on the available data.

Avian Species: The Agency possesses a number of studies on the acute and subacute toxicity of methiocarb to avian species. Although few are sufficient individually to meet Agency requirements, in the aggregate they are sufficient to characterize methiocarb as highly toxic to avian species on an acute basis, but only slightly toxic at most on a subacute basis. Acute toxicities range from 2.47 mg/kg (house finch) to greater than 270 mg/kg (pheasants), with the majority of values falling below 20 mg/kg. When fed in the diet, the subacute toxicity ranges from 1071 (mallard ducks) to >5000 mg/kg (upland game birds).

This difference between the acute and subacute toxicities may be due to reduced food consumption. No feed consumption data were provided for the subacute dietary studies. Results of pen studies suggest that certain formulations may produce a repellency effect in some avian species. Because repellency has not been clearly demonstrated in the available avian toxicity studies, repellency studies are required. At present, hazard to avian species is presumed since a lethal dose is clearly available.

Less than one granule from the registered granular or pelletized bait and seed treatment methiocarb products would contain the acute toxic dose for blackbirds (3.2 mg/kg). Therefore, the use of such products would present a hazard to birds of similar size and sensitivity as the blackbird. Larger birds, such as the mallard duck, would need to ingest 6 to 20 granules to obtain an acute toxic dose. Although repellency data suggest that medium to large size birds may be repelled from treated granules, repellency has not been clearly demonstrated.

Additionally, it is calculated that the application of methiocarb 75% wettable powder at the maximum application rate (4.0 lb ai/A) could result in residues (960 ppm) on the avian forage item, short grass, approaching the mallard dietary toxic dose of 1071 ppm. Application of the product at all application rates could result in residues on short grass exceeding 1/5 the dietary toxic dose (214 ppm). At the maximum application rate, residues on forage/insects are expected to be 230 ppm. The 75% wettable powder is applied as a spray using aerial or ground equipment to avian food items as an avian repellent and insecticide. Residues are therefore expected to be available to birds on a variety of food and forage items.

Field studies are not available, however, to confirm these estimated exposure levels from use of methiocarb 75% WP and full-scale field testing is required. A complete assessment of the potential risk to avian species from registered uses of methiocarb cannot be made until both the repellency studies and the terrestrial field studies are received and evaluated.

Reproduction studies in mallard ducks and bobwhite quail indicate that no reproductive impairment was caused by dosages up to 50 ppm (bobwhite quail) and 100 ppm (mallard duck).

Aquatic Species: The data indicate that technical methiocarb is highly toxic to both coldwater and warmwater fish, and very highly toxic to freshwater invertebrates on an acute basis. The 96-hour acute toxicity to rainbow trout and bluegill sunfish were 0.436 ppm and 0.734 ppm, respectively. The 48-hour studies on freshwater invertebrates showed an acute toxicity of .019 mg/kg.

The available fish early life stage test is not adequate and additional information is required. Aquatic invertebrate life cycle data are not available and are required. The available data on acute toxicity to estuarine and marine organisms are not adequate and new studies are required.

Based on the available data, aquatic estimated environmental concentrations resulting from the use of methiocarb granular or pelletized formulations may pose an acute hazard for aquatic species. The agency used a computer model to simulate runoff from granular applications of methiocarb to turf.

The estimated environmental concentrations (EEC) of methiocarb in the hypothetical ponds and streams of the models ranged from 0.2 ppb to 23.6 ppb. On the basis of methiocarb toxicity to aquatic organisms, the EEC levels may pose an acute hazard to both endangered and nonendangered fish and aquatic organisms.

The EEC's were also calculated for use of the 75% methiocarb wettable powder formulation. In shallow water, the levels ranged from 55.1 ppb to 294 ppb. In deep water, the levels ranged from 4.5 ppb to 24.5 ppb. On the basis of methiocarb toxicity to aquatic species, these levels may pose an acute hazard to both endangered and nonendangered fish and aquatic organisms.

Though these theoretical calculations and modeling indicate that certain uses of methiocarb may result in significant adverse effects to aquatic species, actual field monitoring data are not available to support this finding. Moreover the environmental fate characteristics of methiocarb are not accurately defined by available data. Thus the models can be used only on a limited basis. When environmental fate for methiocarb are available, the models can be refined to more precisely predict the EEC.

Aquatic residue monitoring studies will be required to determine actual residues in aquatic systems exposed to runoff and spray drift. Full scale aquatic organism field testing may be required depending on results of the monitoring studies. The use of methiocarb as a corn seed treatment is not expected to result in aquatic residue levels of concern because corn is planted at a depth of 6 cm in the ground. At this depth, runoff into aquatic systems is likely to be minimal, and is not likely to pose a hazard to exposed aquatic species.

Nontarget Insects: The available data are sufficient to characterize methiocarb as highly toxic to honey bees with high residual toxicity through 3 days posttreatment. The acute contact toxicity for honey bees is determined to be 0.375 micrograms per bee.

Endangered Species: As described above, methiocarb may pose a hazard to endangered birds, insects and aquatic organisms. The U.S. Fish and Wildlife Service has reviewed other chemicals having uses on corn or turf. The use of methiocarb on corn and turf were found to pose potential hazards to some endangered species.

The Agency has developed endangered species labeling, which will be required by separate notice once the Agency receives concurrence from the U.S. Fish and Wildlife Service.

3. Environmental Fate: Few adequate studies are available to evaluate the environmental fate of methiocarb. With the exception of a leaching study for the parent compound on one soil type, and rotational crop studies for grain and root crops, none of the environmental fate data requirements to support the registered uses of methiocarb have been fulfilled.

There are insufficient data to make a determination regarding the potential for methiocarb to reach ground water. Additional data are required including field dissipation and aged leaching studies addressing all the degradates. A full battery of environmental fate data, including hydrolysis, photodegradation, soil metabolism, leaching, soil dissipation and crop and fish accumulation studies are required.

4. Reentry

The available reentry data were inadequate and studies are required to assess the potential exposure to humans entering areas treated with methiocarb. The sampling protocol was inadequate and the data were too variable to adequately assess the dislogeable residues on the tested crop. Studies are required on foliar and soil dissipation as well as dermal and inhalation.

B. SUMMARY OF DATA GAPS

Toxicology - generic

Acute inhalation - rats
21-day dermal toxicity
30-day feeding (dog) with methiocarb sulfoxide
Mouse oncogenicity study
Reproductive effects
Mutagenicity testing
General metabolism study

Residue Chemistry

Livestock metabolism (ruminants and poultry)
Analytical methodology for plants and animals
Data on levels of residues in: citrus fruits, cherries, blueberries, and corn
Tolerance proposals and/or residue data to support the following uses: avocados; pepper and sunflower seed crops; preplant application for agricultural crops, and non-bearing deciduous fruit trees.

Ecological Effects

Field testing for mammals and birds
Avian repellency test
Acute toxicity for estuarine and marine organisms
Fish early life stage
Aquatic invertebrate life cycle
Aquatic residue monitoring

Environmental Fate:

Hydrolysis
Photodegradation - water and soil
Soil metabolism - aerobic and anaerobic
Leaching and adsorption/desorption
Soil dissipation
Confined rotational crop
Fish accumulation
Reentry studies

C. Tolerance Reassessment

Tolerances have been established for residue of methiocarb and its cholinesterase-inhibiting metabolites in or on blueberries, cherries, citrus fruits, corn, and peaches. The tolerances for blueberries and cherries are interim tolerances, due to expire on March 31, 1989. Refer to 40 CFR 180.320.

Commodity	U.S.	Canadian	Mexican	Codex
Blueberries	5.00	-	-	-
Cherries	5.00	-	-	-
Citrus fruits	0.02	-	-	0.05[a/] (proposed)
Corn, forage and fodder	0.03	-	-	-
Corn, fresh	0.03	-	-	0.05[a/] (proposed)
Corn, grain (field and popcorn)	0.03	-	-	-
Peaches	15.00	-	-	-

The food additive tolerances listed for methiocarb under 21 CFR 193.145 and 21 CFR 561.175 were temporary tolerances established to cover residues in or on grape food and feed items resulting from application of the pesticide to grapes under an experimental use permit. These temporary tolerances and the experimental use permit expired on December 31, 1980.

[a/] The sum of methiocarb, its sulfoxide and its sulfone. A decision regarding the potential for compatibility between the pending Codex and the U.S. tolerances for citrus fruits and sweet corn cannot be made until the adequacy of the U.S. tolerances for these commodities has been ascertained.

At present, the methiocarb tolerances are expressed as residues of methiocarb and its cholinesterase inhibiting metabolites. Heretofore, methiocarb, methiocarb sulfoxide and methiocarb sulfone have been considered the residues of concern in both plants and animals. A determination whether other metabolites are considered to be of toxicological concern cannot be made in the absence of adequate metabolism data. The Agency will evaluate the required animal metabolism studies on an expedited basis in order to make this determination as soon as possible. The requirement for additional studies is also contingent upon the results of these animal metabolism studies.

In the event that there are metabolites found in plants that are not found in the animal metabolism studies, additional testing may be required. Also, a determination of whether metabolites in addition to methiocarb and its sulfoxide and sulfone should be sought in plant residue studies as well as in residue analytical methods, cannot be made until animal metabolism studies have been received and evaluated. Such information may be necessary should it be determined that metabolites other than methiocarb's sulfoxide and sulfone are of toxicological concern.

Because of the residue chemistry and toxicology data gaps, the Agency cannot conduct a tolerance reassessment until the required data are submitted and reviewed.

There are several registrations for crops determined to be food uses for which no tolerance exists. Tolerance proposals and supportive residue data are required to support these uses which are as follows: pepper and sunflower crops grown for seed; avocados ; and preplant application for agricultural crops (the crops must be specified).

Additionally, residue data and specification of the intended fruit tree crops must be provided to support the current registered use on "nonbearing deciduous fruit trees."

1. Residue Data.

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of methiocarb. The residues of concern currently included in the tolerance expression include methiocarb, methiocarb sulfoxide and methiocarb sulfone. The Agency can draw no conclusions about the toxicological significance of other plant or animal metabolites at this time.

b. Radiolabeled studies on the uptake, translocation and metabolism of methiocarb in plants which show that methiocarb undergoes two routes of metabolic breakdown in plants. Methiocarb may be oxidized to the sulfoxide (MSO) and thereafter hydrolyzed to methiocarb sulfoxide phenol (MSOP). These metabolites may be further oxidized and hydrolyzed to yield methiocarb sulfone (MSO_2) or methiocarb sulfone phenol (MSO_2P). A secondary metabolic route is the hydrolysis of methiocarb to the phenol (MP).

c. Radiolabeled studies on the metabolism and translocation of methiocarb in cows and chickens. The metabolism of methiocarb in animals is not well understood. Available information again suggests two pathways of metabolism. The major route in both chickens and ruminants appears to be hydrolysis to methiocarb phenol (MP) followed by oxidation to methiocarb sulfoxide phenol (MSOP). Additional metabolism studies in ruminants and poultry are required.

d. Analytical methodology for determining the levels of residues of methiocarb in plants and animals. Two gas chromatographic methods have been proposed for residue collection and enforcement for plants; however, inconsistencies in these methods (significant variation in recoveries and differing extraction methods) preclude the Agency from determining that one or both are adequate. Adequate GC methods exist for the collection of residue data in animals, but an enforcement method must be developed and validated. If additional metabolites of concern are identified in metabolism studies, methods for residue collection and enforcement must be developed.

e. Storage stability data demonstrating that residues of methiocarb are stable in succulent crops for up to one year and in dried grain for up to 3 months. In animals, residues have been shown to be stable for up to two months. No additional data are required at this time; however, if additional metabolites of concern are identified in metabolism studies, storage stability data for those residues will be required.

f. Data on the magnitude and levels of residues of methiocarb in individual raw agricultural commodities, animal products and processed food and feed derived from raw agricultural commodities. Available data are insufficient to determine the adequacy of tolerances in citrus, corn (all varieties), corn fodder and forage, cherries, and blueberries.

Although data have been submitted in support of tolerances in meat and milk, the Agency has not yet determined the adequacy of these data. If additional metabolites of concern are identified in required metabolism studies, additional residue data may be required. Moreover, adequate data are not available for a number of crops that constitute significant sources of animal feed. The Agency's determination will depend on the results of animal metabolism studies and adequacy of data on commodities used for animal feed.

Available data are insufficient to determine the magnitude of residues in processed food and feed items. No processing studies are required at this time. However, processing studies may be required for corn if measurable residues are found at exaggerated rates.

Table A of Appendix I describes residue data requirements in detail.

g. Food and Drug Administration (FDA) Monitoring Data

Total Diet Study Data

From April 1982 to January 1986, a total of 15 market baskets were collected consisting of 72 individual food items per market basket. Out of a total of 1080 samples analyzed throughout these years, only one sample of orange juice from the June 1983 collection date bore measurable residues of methiocarb or its sulfoxide. This sample bore 0.009 ppm of methiocarb (well below the 0.02 ppm tolerance established for citrus fruit). The analytical method used during the collection years was capable of determining methiocarb and its sulfoxide.

Domestic and Import Surveillance Data

No residues exceeding tolerances were found in the FDA domestic surveillance data (1978 to present) for crops having established tolerances for methiocarb.

2. Toxicology Data

The following is a summary of toxicology data reviewed in support of these tolerances.

a. Chronic Toxicity

A 2-year rat feeding study with a NOEL of 100 ppm or 5 mg/kg/day (the highest dose tested) for both systemic effects and cholinesterase inhibition had originally been used to calculate the Acceptable Daily Intake (ADI) for residues of methiocarb. Using a safety factor of 100, the original ADI was 0.05 mg/kg/day. This study, which is now considered a supplementary study, had been used to support the tolerance of 15.0 ppm for peaches and the original 25.0 ppm tolerances for blueberries and cherries.

Subsequently, both a new 2-year rat feeding study and a 2-year dog feeding study were submitted and found acceptable. The new rat study showed a systemic NOEL of 600 ppm (highest dose tested) and a cholinesterase inhibition NOEL of 67 ppm (3.35 mg/kg/day). The lowest effect level (LEL) for cholinesterase inhibition (red blood cell) was 200 ppm. The dosage levels tested were 0, 67, 200, and 600 ppm.

The current ADI for residues of methiocarb is based on the 2-year feeding study in the dog (the most sensitive species). In this study, the NOEL was determined to be 5 ppm based on plasma cholinesterase inhibition and the LEL for cholinesterase inhibition (plasma) was determined to be 15 ppm. At dose levels of 15 ppm and above, plasma cholinesterase activity was depressed 30% or greater. The NOEL and LEL for systemic effects were determined to be 60 ppm (1.5 mg/kg/ day) and 240 ppm (6.0 mg/kg/day), respectively. The highest dose tested (240 ppm) was also the NOEL for brain and erythrocyte cholinesterase inhibition. The dosage levels tested were 5 ppm (reduced from 15 ppm at study week three), 60, and 240 ppm.

Utilizing the NOEL of 5.0 ppm (0.125 mg/kg/day) from the dog study and a safety factor of 10, (for cholinesterase inhibition), the current ADI is 0.0125 mg/kg/day. Based on the established tolerances and a daily food intake of 1.5 kg for a 60 kg individual, the theoretical maximum residue contribution (TMRC) of methiocarb in the daily diet is 0.003575 mg/kg/day and the TMRC is 27.5% of the ADI.

b. Methiocarb sulfoxide

The available toxicity data for methiocarb's metabolite, methiocarb sulfoxide, are inadequate to assess the potential acute toxicological effects which may result from dietary exposure to sulfoxide residues in/on methiocarb treated commodities. A 30-day dog feeding study conducted with methiocarb sulfoxide is required. Results of this study will be considered in the Agency's reassesment of the methiocarb tolerances.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS

1. The Agency is not placing methiocarb into Special Review at this time. Field studies are required to completely assess the potential risk to wildlife, including endangered species.

Rationale:

Based on estimated concentrations of methiocarb on seeds and in granular formulations, current registered uses of the chemical as granular bait formulations and seed treatments theoretically could expose terrestrial organisms to residue levels exceeding risk criteria for special review in 40 CFR 154.7. The information is not sufficient, however, to initiate special review. Full field studies and repellency studies are required to completely assess the hazard posed by these uses.

Theoretical calculations also indicate that the use of certain methiocarb formulations might expose aquatic species to residue levels exceeding risk criteria for Special Review. These calculations, however are based upon models and may not be indicative of actual residue levels in aquatic sites. Aquatic residue monitoring studies will be required to determine actual residues in aquatic systems receiving runoff and spray drift. Upon receipt and evaluation of the monitoring studies, a determination will be made whether full scale aquatic organism field testing will be required or whether regulatory action is appropriate.

2. All outdoor agricultural and commercial uses of methiocarb are restricted for use by certified applicators or workers under their direct supervision on an interim basis pending submittal and evaluation of the required terrestrial field, avian repellency and aquatic residue monitoring studies.

With the exception of the corn seed treatment use, the outdoor uses are restricted due to avian, fish and aquatic organisms toxicity. The corn seed treatment is restricted due to avian toxicity. Those products previously designated as restricted use products (EPA Reg. Nos. 4-254 and 2393-327) will remain as such.

Rationale:

Section 3(d)(1)(C) of FIFRA provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects on the environment."

In the case of methiocarb, the Agency has determined that the commercial and agricultural uses potentially cause adverse effects on avian and aquatic species.

This determination is based on the very high acute toxicity of methiocarb to avian, fish and aquatic species. Calculations utilizing this high acute toxicity and the registered application rates show that avian species could be exposed to a lethal dose of the chemical. Calculations also show that the estimated environmental concentrations of methiocarb residues in the aquatic systems exposed to runoff and drift from registered uses of the chemical may be expected to result in adverse effects to fish and aquatic organisms.

There are no substantiated reports of widespread fish and/or wildlife kills attributed to registered uses of methiocarb. The lack of substantiated fish and wildlife incidents does not serve as evidence that none have occurred. However, it does give the Agency cause to believe that application of methiocarb products by persons knowledgeable in use of the chemical will mitigate the potential risk to nontarget wildlife.

By virtue of the substantially smaller area generally treated by the individual homeowner in relation to that treated by an agricultural or commercial user, it is not expected that the use of methiocarb by the homeowner could cause an adverse effect on the environment.

3. No new permanent tolerances will be granted pending submittal and evaluation of data required to ascertain and validate an appropriate analytical method for the enforcement of tolerances for residues of methiocarb and any metabolites deemed to be of toxicological concern.

Rationale: A review of the various available methods and confirmatory procedures gives the Agency cause to question the appropriateness of the methods available for enforcement of methiocarb tolerances and for collection of residue data in plant commodities.

4. No tolerances may be set for methiocarb in commodities intended for human consumption at residue levels exceeding 5.0 ppm At present, there is one established tolerance over 5.0 ppm (peaches at 15.0 ppm), and the Agency will revoke this tolerance.

Rationale: Tolerances previously established for peaches at 15 ppm, blueberries at 25 ppm, and cherries at 25 ppm based on old studies can no longer be toxicologically supported. The Agency's policy is not to establish tolerances at levels greater than the NOEL.

5. In a separate notice, endangered species labeling will be required for the following methiocarb uses: corn seed treatment, bait application to corn and use on turf (golf courses and sod farms). The notice will be issued after concurrence on the proposed labeling from Fish and Wildlife Service, U.S., Department of Interior.

Rationale: The corn seed treatment, corn bait application and turf (golf courses and sod farms) uses of methiocarb may pose potential hazard to endangered species. In order to protect endangered species in areas where methiocarb is used on corn and turf, endangered species labeling will be required once the Agency receives concurrence from the U.S. Fish and Wildlife Service. At that time, a PR (Pesticide Registration) Notice will be issued in order to notify registrants of the final label requirements for endangered species. Consultation with the U.S. Fish and Wildlife Service will be undertaken to determine whether other uses of methiocarb will jeopardize endangered species.

6. The current label use on "non-bearing deciduous fruit trees" must be revised to specify the fruit tree(s) intended. Residue data must be submitted to support non-food classification or a tolerance.

Rationale: The claim "non-bearing deciduous fruit trees" is too broad.

Previously the use of pesticides on fruit trees (trees which will not bear fruit within one year of application) was considered a non-food use. Current Agency policy is that non-bearing trees are considered a non-food use only if data demonstrate that no detectable residues occur in the crop at the first harvest (one year after application). If residues are detected, then a petition for tolerance with the full range of residue chemistry data requirements will be needed.

7. The current label use as a preplant soil application for agricultural crops must be revised to specify the crops intended. Tolerance proposals and supporting data are required for any crop for which a tolerance has not been established.

Rationale: The term, "agricultural crops", is too broad. There are no tolerances established nor residue data available to cover such a broad use for methiocarb. The current registered use is limited to use in Oregon under a 24(c) special local need state registration which expires in October, 1987.

8. Tolerance proposals and supporting residue data must be submitted to support the use of methiocarb on avocadoes and on pepper and sunflower crops grown for seed.

Rationale: There are no tolerances established nor residue data available to cover such uses.

9. An avian repellency study and an aquatic residue monitoring study are required to support the continued registration of all current outdoor uses of methiocarb.

Rationale: These studies are needed for the completion of the Agency's assessment of the potential risk to both avian and aquatic species resulting from registered uses of methiocarb. Refer to Section A. 2. in Chapter II of this document for a discussion of the potential risks based on available data.

10. The Agency is imposing a 24 hour reentry interval on an interim basis pending submittal and evaluation of the required reentry data. This reentry labeling restriction is being imposed for the use of methiocarb on commercial turf and commercially grown ornamentals; agricultural crops (with the exception of the seed treatment uses), and in greenhouses.

Rationale: Current data are not adequate to establish a definitive reentry interval. Establishment of an interim reentry interval is based on the high acute oral toxicity properties of technical grade methiocarb and the high likelihood of exposure to methiocarb residues of workers who perform activities in the treated sites specified above. It is not expected that the use of methiocarb as a seed treatment would result in exposure to field workers entering fields in which the treated seed has been planted.

11. The Agency is imposing work safety and protective clothing statements for end-use products containing from 20% to 75% methiocarb.

Rationale: These statements are reflective of the dermal toxicity category III of these products and provide specific guidance for persons handling methiocarb products. There are no registered end-use products containing more than 75% methiocarb.

12. A 30-day dog feeding study conducted with methiocarb's metabolite, methiocarb sulfoxide, is required.

Rationale: This study is required to assess the acute hazard potential of methiocarb sulfoxide. In some toxicology studies, methiocarb sulfoxide was shown to be more acutely toxic than methiocarb. The acute toxicities of both methiocarb and methiocarb sulfoxide are associated with cholinesterase inhibition.

13. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.125 - Residue Chemistry

171-4 - Livestock metabolism
171-4 - Analytical method for plant residues

§158.130 - Environmental Fate

162-1 - Aerobic soil metabolism
164-1 - Field dissipation studies - soil
165-1 - Confined rotational crop

§158.135 - Toxicology

81-3 - Acute inhalation
82-1 - 30-days feeding (dog) with methiocarb sulfoxide
85-1 - General metabolism

§158.140 132-1,2,3,4 - Reentry Studies

§158.145 - Ecological Effects

70-1 - Aquatic residue monitoring
70-1 - Avian repellency
71-5 - Actual field testing for mammals and birds
72-4 - Fish early life-stage and invertebrate life cycle

14. While the required data are being developed, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing methiocarb may be sold, distributed, formulated and used subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be reregistered under this Standard, manufacturing-use products (MP's) must contain methiocarb as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this standard, manufacturing-use products (MP's) must contain methiocarb as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing products containing methiocarb provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.

The use patterns currently registered for methiocarb are:

Terrestrial - food: *agricultural crops (preplant); **avocado (soil application); blueberry; cherry; citrus fruits (soil application to bearing trees); **citrus fruits (foliar application on nonbearing trees); corn (seed treatment); **deciduous fruit trees (nonbearing); **peppers (grown for seed); **sunflower (grown for seed).

Terrestrial - nonfood: corn (grown for decorative purposes); crucifers (grown for seed); ornamental plants (including ground cover, flowering plants, shade trees, turf, woody shrubs, and vines); ginseng

Greenhouse - nonfood: ornamental plants

Domestic - outdoor: ornamental gardens; lawns; around building foundations

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*The agricultural crops use is currently registered as a special Local need registration under 24(c) of FIFRA and is limited for use in Oregon only.

** These crops, previously considered nonfood uses must be supported by residue chemistry data for continued registration.

D. REQUIRED LABELING

All products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, and below. Appendix II contains information on label requirements.

Pesticide products containing methiocarb as an active ingredient may not be released for shipment by the registrant after April 30, 1988 unless the product bears amended labeling which complies with the requirement of this Standard.

Pesticide products containing methiocarb as an active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after April 30, 1989 , unless the product bears amended labeling which, approved by EPA, complies with the requirements of this Standard.

Ingredients Statement

The ingredient statement for all methiocarb products must list the active ingredient as:

ACTIVE INGREDIENT(S):

methiocarb (4-methylthio-3,5-
xylylmethylcarbamate)...................... _____%

1. Manufacturing-Use Products

In addition to the appropriate precautionary labeling designated in 40 CFR 162.10, the labels of all manufacturing-use products must contain the following statements:

- For formulation into end-use insecticide: molluscicide; acaricide; bird repellent; rodent repellent [specify one or more] products intended for [specify the appropriate use pattern/uses listed in section C.3.].

- This pesticide is toxic to fish and very highly toxic to birds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

2. End-Use Product Labeling

a. The following statement must appear on the front panel of end-use labeling for use of methiocarb as a corn seed treatment.

RESTRICTED USE PESTICIDE
Due to Avian Toxicity

> For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

b. The following statement must appear on the front panel of end-use labeling for current registered outdoor commercial and agricultural uses of methiocarb other than the corn seed treatment use.

RESTRICTED USE PESTICIDE
Due to Avian Toxicity and Fish and Aquatic
Organism Toxicity

> For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

c. Methiocarb products intended for outdoor use must bear the following statement on the product label:

> This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

d. The following statements must appear on labeling for the following specified uses:

Outdoor Uses Other Than Granular and Pelletized Bait and Seed Treatment

This pesticide is toxic to fish and very highly toxic to birds. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Granular or Pelletized Bait for Molluscicide Use

This pesticide is toxic to fish and very highly toxic to birds. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Seed Treatment

This pesticide is toxic to fish and very highly toxic to birds. Cover and incorporate spills. Do not contaminate water by cleaning equipment or disposal of wastes.

e. The following statement must appear on the labeling for commercial turf and commercially grown ornamentals; agricultural crops (with the exception of seed treatments); and in greenhouses.

> Do not enter treated areas for 24 hours after application unless protective clothing is worn.

f. The following protective clothing and work safety rules must appear on labeling for end-use products containing from 20% to 75% methiocarb.

> REPEATED OR PROLONGED EXPOSURE TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY CAUSE SUSCEPTIBILITY TO ADVERSE EFFECTS FROM VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.
>
> Keep all unprotected persons, livestock, and pets away from treated areas or where there is danger of drift.
>
> Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away, See First Aid (Practical Treatment) Section of the label.
>
> WEAR THE FOLLOWING PERSONAL PROTECTIVE EQUIPMENT DURING MIXING, LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING/LOADING/APPLICATION EQUIPMENT, DISPOSAL OF THE SPRAY SOLUTION, AND EARLY REENTRY INTO TREATED AREAS BEFORE [SPRAYS HAVE DRIED or DUST HAVE SETTLED, as applicable]: long sleeve shirt, long pants, shoes, socks, chemical-resistant gloves.
>
> IMPORTANT! Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

(continued next page)

> AFTER WORK: Before removing gloves, wash them with soap and water. Wash hands, face, and arms with soap and water. Launder all clothing worn during use with this product before reusing. Launder this clothing separately from household clothing. Clothing or gloves that have been heavily contaminated or drenched must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

g. In addition to the statements specified in item f., above, products containing from 20% through 75% methiocarb with directions for aerial application must bear the following label statements.

> DURING AERIAL APPLICATION, HUMAN FLAGGERS MUST BE IN TOTALLY ENCLOSED VEHICLES.
>
> Aerial applicators are not required to wear chemical resistant gloves if in an enclosed cockpit.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

William H. Miller (PM 16)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation 1/	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All			Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All			Yes	12 Months
62-2 - Certification of Limits	TGAI	All			Yes 3/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All			Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All			Yes	6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation 1/	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-3 - Physical State	TGAI	All			Yes	6 Months
63-4 - Odor	TGAI	All			Yes	6 Months
63-5 - Melting Point	TGAI	All			Yes	6 Months
63-6 - Boiling Point	TGAI	All			No 4/	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All			Yes	6 Months
63-8 - Solubility	TGAI or PAI	All			Yes	6 Months
63-9 - Vapor Pressure	PAI	All			Yes	6 Months
63-10 - Dissociation Constant	PAI	All			Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All			Yes	6 Months
63-12 - pH	TGAI	All			No 5/	
63-13 - Stability	TGAI	All			Yes	6 Months
Other Requirements						
64-1 - Submittal of Samples	TGAI, PAI	All			Reserved 6/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.120 Product Chemistry Footnotes

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following issuance of this Registration Standard, unless otherwise indicated.

3/ The product chemistry data submission under 62-2 must also include the following: All nitrosamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosamines found.

4/ Not required since technical methiocarb is a solid at room temperature.

5/ Not required since technical methiocarb is not soluble enough in water.

6/ If samples are needed, the Agency will request them.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for 1/ Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity 2/					
171-3 - Directions for Use		(See index)			
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Yes	00036496, 00116555, 00124968, 00125530, 00155046, 00155055, 00155057.	No	
- Livestock	PAIRA	Partially	00046450, 00046451, 00116555, 00125528, 00155057.	Yes3/4/	18 months
171-4 - Residue Analytical Method					
- Plant Residues	TGAI & Metabolites	Partially	00035520, 00035522, 00035524, 00046448, 00046453, 00056045, 00115224, 00116555,	Yes 5a/5b/	5a/ - 15 months 5b/ - Dec. 31, 1987

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.125 Residue Chemistry (continued)					
171-4 - Residue Analytical Method (continued)			00125530, 00125532, 00125537, 00127630, 00127632, 00127634, 00155057, GS0577001.		
- Animal Residues	TGAI & Metabolites	Yes	00116555, 00125532, 00127630, 00154537, 00155057, GS0577002.	No[7]	
171-4 - Storage Stability Data	TEP & Metabolites	Partially	00046449, 00056047, 00116555, 00125530, 00127630, 00158770.	Reserved[6]	
171-4 - Magnitude of the Residue - Crop Field Trials					
- Citrus Fruits Group	EP	Partially	00056044.	Yes [8][9][10]	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.125 Residue Chemistry (continued)					
171-4 - Magnitude of the Residue - Crop Field Trials (continued)					
- Stone Fruits Group 11/					
o Cherries	EP	Partially	00123980, 00158770.	Yes 12/13/14/ 15/16/	
o Peaches 17/			00123980.		
- Small Fruits and Berries Group 18/					
o Blueberries	EP	Partially	00127628, 00127635, 00155057, 00158770.	Yes 19/20/21/22/	
- Cereal Grains 23/ Group					
o Corn, Fresh and Field (Including Popcorn)	TEP	Partially	00035523, 00037132, 00155042, GS0577003.	Yes 24/25/26/27/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.125 Residue Chemistry (continued)					
171-4 - Magnitude of the Residue - Crop Field Trials (continued)					
- Forage, Fodder and Straw of the Cereal Grains Group 28/					
o Corn Forage, Fodder and Silage	TEP	Partially	00035523, 00037132, 00155042.	Yes 29/	
- Meat/Milk/Poultry/ Eggs	—			Reserved 30/	
- Miscellaneous Crops					
° Deciduous Fruit Trees (non-bearing)	TEP	No		Yes 31/	
° Peppers and Sunflowers Grown for Seed	TEP	No		Yes 32/	
° Avocadoes	TEP	No		Yes 33/	
° Agricultural Crops (preplant application)	TEP	No		Yes 34/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes

1/ Due dates refer to the number of months following issuance of the Registration Standard, unless otherwise indicated.

2/ Refer to Product Chemistry Data Requirement tables.

3/ Metabolism studies utilizing ruminants and poultry are required. Animals must be dosed for 3 days with ringlabeled [^{14}C]methiocarb at a level sufficient to permit complete characterization of ^{14}C residues. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Should the metabolism of methiocarb in ruminants and poultry be found to differ significantly, studies of swine metabolism may be required.

4/ Samples from studies required in footnote 3 should be analyzed using the GC method described in Mobay Chemical Company's Report No. 49078 (or an appropriate substitute which may be used for enforcement purposes) to ascertain the usefulness of the method for enforcement purposes.

5a/ Residues of methiocarb sulfone in or on crop samples must be subjected to analysis by the multiresidue protocols. Protocols for methods I, II, III, and IV are available from National Technical Information Service under Order No. PB 203734/AS.

5b/ The following must be submitted: a side-by-side comparison of the PAM II procedure (Mobay Report No. 25168), the confirmatory method in Report No. 27147, and the method in Report No. 45089 using incurred residues. These additional data requirements were previously imposed on the sponsor of the data in the Agency letter dated June 12, 1986. Therefore, the submittal due date for the data reflects the timeframe imposed in that letter. The data due by December 31, 1986 (an explanation as to why no HCl is used in the extraction solvent in the method in Report No. 45089) have been submitted and are currently under evaluation by the Agency. If it is determined that plant metabolites in addition to the sulfoxide and sulfone are of toxicological concern, valid enforcement methods to determine such metabolites must be submitted.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes (continued)

6/ If the requested animal metabolism data and toxicology data indicate metabolites of concern in addition to the sulfoxide and sulfone, data depicting the stability of these metabolites in frozen plant and animal tissues will be required.

7/ Adequate gas chromatographic methods are available for collection of data pertaining to methiocarb residues of current concern in animal tissues. Refer to footnote 4 regarding the data needed to ascertain the usefulness of the method for enforcement purposes.

8/ Data depicting methiocarb residues of concern in or on oranges, lemons, and grapefruit harvested 1 year after the last of four foliar applications (by ground equipment) of the 75% WP at 1.5 lb ai/A/application on nonbearing citrus trees. An adequate residue analytical method must be used for collection of data. Tests on oranges must be conducted in FL(69%) and CA(29%) (State production percentages follow abbreviations parenthetically); grapefruit tests must be conducted in FL(76%), CA(14%), and TX(6%); and lemon tests must be conducted in CA(81%) and AZ(19%) (Agricultural Statistics, 1985, p. 198). Data must be submitted within 30 months of Agency notification of an approved residue analytical method.

9/ If the method in Mobay Report No. 45089 is found to be invalid, data are required depicting methiocarb residues of concern in or on oranges, lemons, and grapefruit harvested after the last of two broadcast soil applications (by ground equipment) with the 2% G or the 2% P/T formulations (in separate tests) at 0.94 lb ai/A using an adequate residue analytical method for data collection. Tests must be conducted in CA where use of these formulations is permitted under EPA SLN's CA780040, CA780116, CA780158, CA790146, and CA790249. Alternatively, if the method in Report No. 45089 is found to be valid, it must be ascertained that the method has been validated at the tolerance level of 0.02 ppm. (Presently, the lowest fortification level tested is 0.05 ppm.) Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

Testing with the 2% formulation at 0.94 lb. a.i./A as described in the preceeding paragraph would suffice for residue testing required to support the existing 1% granular formulations registered under Section 3 of FIFRA. This Section 3 registered product has an application rate of up to 0.5 lb. a.i./A applied as a soil application and may be applied in states other than California. Testing with the 1% granular formulation would be needed should registrants choose not to support the 2% granular formulation. Tests must then be conducted on oranges in Florida and California; on grapefruit in Florida, California and Texas; and on lemons in California and Arizona. All residue data must be collected using an adequate analytical method. Data must be submitted within 18 months of Agency notification of an approved analytical method.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes (continued)

10/ Residues must be determined in pulp (dehydrated), molasses, oil, and juice processed from citrus fruit bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed. It may be necessary to use exaggerated rates to obtain measurable residues in the raw agricultural commodity. Data must be submitted within 36 months of Agency notification of an approved residue analytical method.

11/ The following additional items would be needed to support a crop group tolerance should such a tolerance be sought. Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group members peaches and plums (fresh prunes).

12/ Because both methods used to collect data are currently being evaluated, data requirements will be contingent upon the adequacy of the methods. If the Mobay method designated in Report No. 25168 is judged adequate then data requirements in 13/ below must be met. If the method designated in Report No. 45089 is judged adequate and that in Report No. 25168 is inadequate, the data requirements in 14/ below must be met. If both methods are judged inadequate, then data requirements in 15/ and 16/ below must be met.

13/ The 24(c) registrants must propose reduced use rates, reduced seasonal use rates, and/or an increased PHI, and submit appropriate supporting data from studies conducted in CA, UT, NY, and WA. These data must be submitted within 18 months of Agency notification of an approved residue analytical method. Also, the section 3 registrants must provide the gal/A applied in Mobay Report No. 31440. Information on the gal/A applied has been submitted and is currently under evaluation by the Agency.

14/ Data depicting residues of concern in or on cherries harvested 7 days following the last of three foliar applications of the 75% WP formulation at 4 lb ai/A/application. Applications must begin when cherries begin to ripen and must be repeated at 7-day intervals. The tests must reflect full cover sprays applied using ground equipment and, in separate tests, aerial sprays in > 5 gal/A. Tests must be conducted in CA, NY, UT, and WA to support the uses permitted under SLN's CA770034, NY770003, UT790001, and WA770015. The data will also support EPA SLN No. CA770161. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

15/ Data depicting residues of concern in or on cherries harvested 7 days following the last of three foliar applications of the 75% WP formulation at 4 lb ai/A/application. Applications must be made when cherries begin to ripen and must be repeated at 7-day intervals. The tests must reflect full cover sprays applied using ground and aerial equipment, in separate tests, using a minimum of 5 gal/A. Tests must be conducted in CA, NY, UT, and WA (EPA SLN Nos. CA770034, NY770003, UT790001, and WA770015). Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes (continued)

16/ Data depicting residues of concern in or on cherries harvested 3 days after a single foliar application of the 75% WP at 1.5 lb ai/A using both ground and aerial equipment in separate tests. Ground applications should be made using 300 gal/A and aerial applications should be made in a minimum of 5 gal/A. Tests on sweet cherries must be conducted in WA(37%) and MI(18%), and those on tart cherries must be conducted in MI(77%) and NY(10%) which produced 48% and 87%, respectively, of the 1984 sweet and tart cherry crops (Agricultural Statistics, 1985, p. 194). Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

17/ There is an established tolerance for peaches, and the cited data were submitted in support of the tolerance. However, the adequacy of these data cannot be determined since there are currently no existing Use Directions for peaches.

18/ The following additional items would be needed to support a crop group tolerance should such a tolerance be sought. Use directions must be proposed, and appropriate supporting residue data submitted for one additional representative group member (cranberries). It is noted that tolerances for the following additional crop members of this group have been proposed: grapes, raspberries, and strawberries.

19/ Because both methods used to collect data are currently being evaluated, data requirements will be contingent upon the adequacy of the methods. If the Mobay method designated in Report No. 45089 is judged adequate, then data requirements in 20/ below must be met. If the method in Report No. 25168 is judged adequate, then data requirements in 21/ below must be met. If neither method is found to be adequate, then data requirements in 22/ below must be met.

20/ The 24(c) registrants must propose reduced use rates, reduced seasonal use rates, and/or an increased PHI and submit appropriate supporting data. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

21/ The 24(c) and section 3 registrants must propose reduced use rates, reduced seasonal use rates, and/or an increased PHI and submit appropriate supporting data. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes (continued)

22/ Data depicting methiocarb residues of concern in or on blueberries harvested on the day of the last of three foliar applications of the 75% WP at 2 lb ai/A. Applications must be made using ground and aerial equipment, in separate tests, at treatment intervals of 7 days. An adequate residue analytical method must be used. Tests must be conducted in AR, IN, NH, NY, OR, PA, VT, and WA to support appropriate SLN registrations. Data must be submitted within 18 months of Agency notification of an approved residue anlytical method.

23/ The following additional items would be needed to support a crop group tolerance should such a tolerance be sought. Use directions must be proposed, and appropriate supporting residue data submitted, for additional representative group members (sorghum and wheat). It is noted that a tolerance for rice grain has been proposed.

24/ Because both methods used to collect data are currently being evaluated, data requirements will be contingent, in part upon the adequacy of the methods. If the method designated in Report No. 45089 is judged adequate, data requirement in 25/ below must be met. If the method in Report No. 25168 or neither method is deemed adequate, data requirement in 26/ below must be met.

25/ Data depicting adequate recovery of methiocarb residues of concern from corn grain fortified at 0.03 ppm, using the method in Report No. 45089. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

26/ Data depicting methiocarb residues of concern in or on corn grain (field and popcorn) and fresh corn (including sweet corn kernels and cobs) harvested after the following application schedule: seed treatment with a D , formulation at 0.5 lb ai/100 lb seed; and one broadcast application per season of a WP formulation at 0.1 lb ai/20 lb. cracked corn (carrier)/A. Tests must reflect an 80-day PHI. Tests must be conducted in DE, IN, MD, MI, NY, OH, PA, VA, and WV (where bait uses are registered). All residue data must be collected using an adequate analytical method. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

27/ If the method in Report No. 45089 is deemed adequate, no processing studies are required. However, if the method is deemed inadequate, the field trails requested in 26/ should include exaggerated rates (10 to 25X). If no measurable residues occur at exaggerated rates, no processing data will be required. Data must be submitted within 24 months of Agency notification of an approved residue analytical method.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes (continued)

28/ The following additional items would be needed to support a crop group tolerance should such a tolerance be sought. Use directions must be proposed and appropriate supporting residue data submitted for additional representative group members (wheat and one additional cereal grain). It is noted that a tolerance for rice straw has been proposed.

29/ Data depicting methiocarb residues of concern in or on corn forage and fodder, harvested after the following application schedule: seed treatment with a D formulation at 0.5 lb ai/100 lb seed and one broadcast application per season of a WP formulation at 0.1 lb ai/20 lb cracked corn (carrier)/A. Fodder samples must reflect an 80-day PHI and forage samples must be collected at intervals following the bait application or at a pregrazing interval to be proposed by the registrant. Residue data must be collected using an adequate analytical method which has been validated to 0.03 ppm. Tests must be conducted in DE, IN, MD, MI, NY, OH, PA, VA, and WV (where bait uses are registered). Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

30/ There are no tolerances established for these commodities. Because there are numerous data gaps concerning the magnitude of the residue in feed items of animals, as well as the nature of the residue in animals, no determination may be made at the time regarding the adequacy of the available data nor the need for the establishment of tolerances for these commodities.

31/ Residue data and specification of the intended fruit tree crops must be provided to support the current registered use on non-bearing deciduous fruit trees (trees which will not bear fruit within 1 year of application). Refer to 171-12(d) regarding food use/non-food use determination for non-bearing crop use. All residue data must be collected using an adequate analytical method. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

32/ Tolerance proposals and supportive residue data are required to support the uses on pepper and sunflower crops grown for seed. All residue data must be collected using an adequate analytical method. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.125 Residue Chemistry Footnotes (continued)

33/ Tolerance proposal and supportive data are required to support current use on avocadoes. The current use on this crop is a soil application with a restriction not to allow formulation to come in contact with edible portions of plants. All residue data must be collected using an adequate analytical method. Data must be submitted within 18 months of Agency notification of an approved residue analytical method.

34/ The agricultural crops must be specified. Tolerance proposals and supportive data are required to support those crops for which no methiocarb tolerances exist. The current use is a 24(c) for use in Oregon only. All residue data gathered must be collected using an adequate analytical method. Data must be submitted within 18 months of an approved residue analytical method.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,F,H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B,F	No		Yes	May 1987 2/
161-3 - On Soil	TGAI or PAIRA	A	No		Yes	May 1987 2/
161-4 - In Air	TGAI or PAIRA		No		No 3/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,F,H	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA		No		No 4/	
162-4 - Aerobic Aquatic	TGAI or PAIRA		No		No 4/	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B,F	Partially 5/	00145802	Yes	August 1987 2/
163-2 - Volatility (Lab)	TEP		No		No 3/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.130 Environmental Fate (continued)						
163-3 - Volatility (Field)	TEP		No		No 3/	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No		Yes	November 1988 2/
164-2 - Aquatic (Sediment)	TEP		No		No 4/	
164-3 - Forestry	TEP		No		No 4/	
164-4 - Combination and Tank Mixes	TEP		No		No 6/	
164-5 - Soil, Long-Term	TEP	A	No		Reserved 7/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	November 1989 2/
165-2 - Rotational Crops (Field)	TEP	A	Partially	GS0577004 GS0577005	Reserved 8/	
165-3 - Irrigated Crops	TEP		No		No 4/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.130 Environmental Fate (continued)						
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP		No		No 4/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.130 Environmental Fate Footnotes (continued)

1/ Due dates refer to the number of months following issuance of the Registration Standard, unless otherwise indicated.

2 / These data requirements were previously imposed as part of the Agency's Call-In Notice of August 1986. Therefore, these submittal due dates reflect the timeframes imposed in that Call-In Notice.

3/ Not required based on the low vapor pressure of methiocarb.

4/ The 162-4 and 165-3 data requirements were imposed under the Agency's Data Call-In Notice of August 1986. It has subsequently been determined that they (as well as the 162-3, 164-2, 164-3 and 165-5) are not required becau the current registered uses do not include any aquatic, forestry, or aquatic impact use sites.

5/ This study (MRID No. 00145802) is acceptable to fulfill the data requirement for the parent compound for one soil type only.

6/ Tank mix data requirements are not being imposed by this Standard.

7/ Soil long-term study is reserved pending the results of aerobic soil metabolism and field dissipation studies.

8/ Additional data requirements are reserved pending results of the confined data required under 165-1.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	TGAI	A,B,F,H	Yes	00036477, 00083437	No	
81-2 - Acute Dermal	TGAI	A,B,F,H	Yes	00036478	No	
81-3 - Acute Inhalation - Rat	TGAI	A,B,F,H	No		Yes	6 Months
81-7 - Acute Delayed Neurotoxicity - Hen	--	--	Yes 2/	--	No	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding -						
Rodent	TGAI	A	No		No 3/	
Non-rodent	TGAI	A	No		No 3/	
- 30-Day Feeding - Non-rodent (Dog)	Methiocarb Sulfoxide	A,B,F,H	No		Yes 7/	6 Months (approved protocol)
82-2 - 21-Day Dermal	TGAI	A,B,F,H	No		Yes	6 Months
82-3 - 90-Day Dermal	--	--	No		No 4/	
82-4 - 90-Day Inhalation	--	--	No		No 5/	
82-5 - 90-Day Neurotoxicity	--	--	No		No 6/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.135 Toxicology (continued)						
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
Rodent	TGAI	A	Yes	00115226	No	
Nonrodent	TGAI	A	Yes	00128939, 00149362	No	
83-2 - Oncogenicity Study -						
Rat	TGAI	A	Yes	00115226	No	
Mouse	TGAI	A	No		Yes 8/	50 Months
83-3 - Teratogenicity -						
Rat	TGAI	A,B,F,H	Yes	00124617	No	
Rabbit	TGAI	A,B,F,H	Yes	00143213	No	
83-4 - Reproduction -	TGAI	A,B,F,H	No		Yes	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI	A,B,F,H	No		Yes	9 Months
84-2 - Chromosome Aberration	TGAI	A,B,F,H	No		Yes	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,F,H	No		Yes	12 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.135 Toxicology (continued)						
SPECIAL TESTING						
85-1 - General Metabolism	PAIRA	A	No		Yes	24 Months
85-2 - Domestic Animal Safety 5/						
85-3 - Dermal Absorption 5/						

§158.135 Toxicology Footnotes (continued)

1/ Due dates refer to the number of months following issuance of the Registration Standard, unless otherwise indicated.

2/ Not required because methiocarb is not an organophosphate. Nonetheless, there is an adequate study available (MRID No. 83438) which is negative for acute delayed neurotoxicity.

3/ 90-day feeding studies are not being required because there are adequate chronic studies available.

4/ Not required because existing use-patterns as described in this document do not result in repeated skin contact for an extended period of time.

5/ These data are not required for the current use patterns.

6/ Not required because methiocarb is not an organophosphate.

7/ No effect levels and lowest effect levels for plasma, erythrocyte, and brain cholinesterase inhibition must be determined. The protocol must be submitted for evaluation prior to initiation of the study. The study must be submitted within 18 months of acceptance of the protocol by the Agency.

8/ Registrants who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in subchronic or range finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirement.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,F	No		Yes	December, 1987
132-2 - Soil Dissipation	TEP	A,B,F	No		Yes	December, 1987
133-3 - Dermal Exposure	TEP	A,B,F	No		Yes	December, 1987
133-4 - Inhalation Exposure	TEP	A,B,F	No		Yes	December, 1987

1/ Methiocarb was subject to a special call-in notice for reentry data dated May 27, 1986. These due dates reflect the time frames imposed in that call-in notice.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Acute Oral Toxicity	TGAI	A,B,F,H	Yes	GS0577006	No	
71-2 - Avian Subacute Dietary						
A. Upland Game Bird	TGAI	A,B,H	Yes	00022923	No	
B. Waterfowl	TGAI	A,B,F,H	Yes	00022923	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B	No		No 2/	
71-4 - Avian reproduction						
A. Upland Game Bird	TGAI	A,B,H	Yes	00128119	No	
B. Waterfowl	TGAI	A,B,H	Yes	00128119	No	
71-5 - Simulated or Actual Field Testing for Mammals and Birds	TEP	A,B,H	No		Yes 3/	6 Months (Acceptable Protocol)
70-1 - Special Test, Avian Repellency	TGAI	A,B,H	No		Yes 4/	April, 1988 11/

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 1/
§158.145 Wildlife and Aquatic Organisms (continued)						
AQUATIC ORGANISMS TESTING						
72-1 - Freshwater Fish Toxicity						
A. Warmwater	TGAI	A,B,H	Yes	00150628	No	
	TEP	A,B,H	Yes 10/		No	
B. Coldwater	TGAI	A,B,F,H	Yes	00150628	No	
	TEP	A,B,F,H	Yes 10/		No	
72-2 - Acute Toxicity to Aquatic Invertebrates	TGAI	A,B,F,H	Yes	00127638	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
Fish	TGAI	A,B	No		Yes 5/	August 1987 11/
Shrimp	TGAI	A,B	No		Yes 5/	August 1987 11/
Oysters	TGAI	A,B	No		Yes 5/	August 1987 11/
72-4 - Fish and Early Life-Stage and Aquatic Invertebrate Life Cycle						
Fish	TGAI	A,B	Partial 6/	00155967	Yes 6/	November 1987 11/
Invertebrates	TGAI	A,B	No		Yes	November 1987 11/
72-5 - Fish Life Cycle	TGAI	A,B	No		Reserved 7/	
72-6 - Aquatic Organism Accumulation	TGAI	A,B	No		No 2/	
72-7 - Simulated or Actual Field Testing for Aquatic Organisms	TEP	A,B	No		Reserved 8/	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance		Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
70-1 - Special Test, Aquatic Residue Monitoring	TEP	A,B	No		Yes 9/	April 1988 11/

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.145 Wildlife and Aquatic Organisms Footnotes

1/ Due dates refer to the number of months following issuance of the Registration Standard, unless otherwise specified.

4/ Not currently a requirement.

/ Terrestrial field studies as described below will be required to support registered uses of methiocarb.

To support registration of granular and pelletized bait products: A study must be conducted using the 2% granular bait formulation at the maximum label rate (0.94 ai/A) and the maximum number of minimally spaced repeat applications. The purpose of this study will be to determine whether the use of these products could result in wildlife kills. Studies conducted at maximum application rates on citrus in California using ground equipment or as a preplant soil application in Oregon using aerial equipment would be acceptable. Seven treatment fields and a control field should be selected for study. Treatment fields should be at least 50 acres in size. The study will require 1 year of observations. A 3- to 4-month pretreatment period of baseline observations should be included in the study design. During the baseline study period, observations of the abundance and distribution of bids and all other nontarget species within the study areas should be recorded. during the treatment period, methiocarb must be applied using the maximum number of minimally-spaced repeat applications. Posttreatment mortality and toxic symptoms among all nontarget species must be observed and recorded. Blood, brain, and carcass analysis for residues and cholinesterase inhibition should be conducted. Soil, vegetation, and nontarget insects should be monitored for methiocarb residues. Carcass search efficiency must also be determined and documented. A study protocol must be submitted for review prior to initiation of the study.

To support registration of methiocarb dust, and corn treatment and cracked corn bait, and other methiocarb seed treatments: A field study to determine the wildlife population reduction hazard from the use of cracked corn treated with methiocarb as a molluscide is required. This study must also be conducted to support the use of methiocarb seed corn treatment and other seed treatments used to repel birds. A primary objective of this study will be to determine the hazard to birds from the use of methiocarb cracked corn mollusicide and seed treatment to repel birds. The study will require the selection of a study site typical of corn-growing regions (i.e., Illinois or Iowa). Within the geographical site at least two treatment plots and two control plots should be selected for study. These plots should be at least 150 acres in size. The study will require 2 years of observations. During the first year, baseline observations should include observation of the abundance and distribution of birds and other nontarget organisms present within the study areas. All test sites (biotic and abiotic components) should be screened for pesticide residues during the first year of the study. No methiocarb should be applied during the first year. During the second year, methiocarb cracked corn slug bait

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

§158.145 Wildlife and Aquatic Organisms Footnotes (continued)

should be used at the maximum rate (0.1 lb/10 lb cracked corn/A), with the maximum number of minimally-spaced repeat applications. Observations of the abundance and distribution of all nontarget species within the study areas should be recorded. Blood, brain, and carcass analysis for residues and cholinesterase inhibition should be conducted. Birds and nontarget species exhibiting toxic sublethal symptoms should be sampled and monitored for continued toxic symptoms, eventual recovery or death, and pesticide residues, as well as cholinesterase inhibition. Soil, vegetation, nontarget insects, and water should be monitored for residues resulting from application of methiocarb. Carcass search efficiency must also be determined and documented. A protocol must be submitted for review prior to study initiation.

To support registration of methiocarb 75% WP (all uses). A field study will be required to support all uses of methiocarb 75% wettable powder. The purpose of this study will be to measure wildlife mortality associated with the use of methiocarb 75% wettable powder as an avian repellent and insecticide. Studies conducted at the maximum application rate (4.0 lb ai/acre) on blueberries and cherries would be acceptable. Two geographically different sites should be selected and cherry-growing sites in the States of California and Michigan should be selected. At each geographic site, seven treatment plots and a control plot of at least 50 acres in six should be selected. The study will require 1 year of observation. A 3 to 4 month pretreatment period of baseline observation should be included in the study design. During the baseline study period, observations of the abundance and distribution of birds and all other nontarget species within the study areas should be recorded. During the treatment period, methiocarb must be applied using the maximum number of minimally-spaced repeat applications. Posttreatment mortality and toxic symptoms among all nontarget species must be observed and recorded. Blood, brain, and carcass analysis for residues and cholinesterase inhibition should be conducted. Soil, vegetation, and nontarget insects should be monitored for methiocarb residues. Carcass search efficiency must also be determined and documented. A study protocol must be submitted for review prior to initiation of the study.

4/ Avian repellency studies should be conducted according to ASTM guidelines for comparative acute and long-term oral or gustatory avian repellency studies (ASTM Designation E657-78). A protocol for this study has been received and is currently under evaluation by the Agency.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.145 Wildlife and Aquatic Organisms Footnotes (continued)

5/ Required to support the use of this product on corn, turf, fruit crops, and other uses associated with coastal counties.

6/ The study partially fulfills the requirement. If data describing water temperatures in each test tank are submitted and show that no significant variance in temperature occurred in any of the tanks, the study may be upgraded.

7/ A requirement for this study is reserved pending the results of the fish early life stage study.

8/ Requirements for aquatic field studies are reserved pending the results of aquatic residue monitoring studies.

9/ Residue data on methiocarb and its major metabolites are required in order to determine exposure levels in receiving waters adjacent to use sites. Residues in water resulting from the use of granular or pelletized baits, treated corn and seeds, and the 75% wettable powder must be described. These studies could be conducted simultaneously with the terrestrial field studies cited in footnote 3 required to support each use. Residue monitoring studies must incorporate the following design characteristics: 1) The percentage of the drainage area under treatment should be provided. Topographical maps showing the relationship of the sampling sites to untreated areas within each watershed should be specified. 2) Soil characteristics of the fields being monitored should be specified. 3) Analytical methodology used to measure the residues of methiocarb must be given. The chemical detection of residues must be quantified by the most sensitive methodology available. 4) In addition to water samples, the hydrosoil (top 0.5 inch only) must be sampled at all stations. 5) Sampling stations at each site should be located in adjacent bodies of water (i.e., drainage ditches, waterways, and canals). Runoff from fields should also be measured. A protocol for this study has been received and is currently under evaluation by the Agency.

10/ Though the available studies(MRID No. 00036484) have been found to be acceptable, they are not required to support continued registration of the current uses of methiocarb because a) methiocarb is not registered for direct application to water, and b) aquatic residues resulting from the registered uses are not expected to exceed the acute toxicity level of the technical material to fish.

11/ These data requirements were previously imposed as part of the Agency's Call-In Notice of August 1986. Therefore, these submittal due dates reflect the timeframes imposed in that Call-In Notice.

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee Acute Contact Toxicity	TGAI	A,B	Yes	00036935	No
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	A,B	Yes	00060625	No
141-4 - Honeybee Subacute Feeding Study	Reserved 1/				
141-5 - Field Testing for Pollinators	TEP	A,B	No		No 2/
NONTARGET INSECT TESTING - AQUATIC INSTECTS:					
142-1 - Acute Toxicity to Aquatic Insects	Reserved 3/				
142-2 - Aquatic Insect Life Cycle Study	Reserved 3/				
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved 3/				
143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES	Reserved 3/				

TABLE A

GENERIC DATA REQUIREMENTS FOR METHIOCARB

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§158.155 Nontarget Insect Footnotes

1/ Reserved pending development of test methodology.

2/ This data requirement is imposed only on a case-by-case basis. Data reviewed under the Standard do not indicate the need for a field study.

3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation 1/	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	MP	All			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All			Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	All			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All			Yes	12 Months
62-2 - Certification of Limits	MP	All			Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All			Yes	12 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation 1/	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics						
63-2 - Color	MP	All			Yes	6 Months
63-3 - Physical State	MP	All			Yes	6 Months
63-4 - Odor	MP	All			Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All			Yes	6 Months
63-12 - pH	MP	All			Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP	All			Yes	6 Months
63-15 - Flammability	MP	All			Yes	6 Months
63-16 - Explodability	MP	All			Yes	15 Months
63-17 - Storage Stability	MP	All			Yes	6 Months
63-18 - Viscosity	MP	All			Yes	6 Months
63-19 - Miscibility	MP	All			Yes	15 Months
63-20 - Corrosion Characteristics	MP	All				

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHIOCARB

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation 1/	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry (continued)						
Other Requirements:						
64-1 - Submittal of Samples	MP	All			Reserved 3/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following issuance of this Registration Standard, unless otherwise indicated.

3/ If samples are needed, the Agency will request them.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHIOCARB

Data Requirement	Test Substance	Does EPA Have Data?1/	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	MP			Yes 3/	6 Months
81-2 - Acute Dermal	MP			Yes 3/	6 Months
81-3 - Acute Inhalation - Rat	MP			Yes	6 Months
81-4 - Eye Irritation - Rabbit	MP			Yes	6 Months
81-5 - Dermal Irritation - Rabbit	MP			Yes	6 Months
81-6 - Dermal Sensitization - Guinea Pig	MP			Yes	6 Months

1/ Although product specific toxicity data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product.

2/ Due dates refer to the number of months following issuance of this Registration Standard.

3/ If the MP is a technical grade active ingredient, refer to the Toxicology Table A for data requirements which may have been satisfied.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

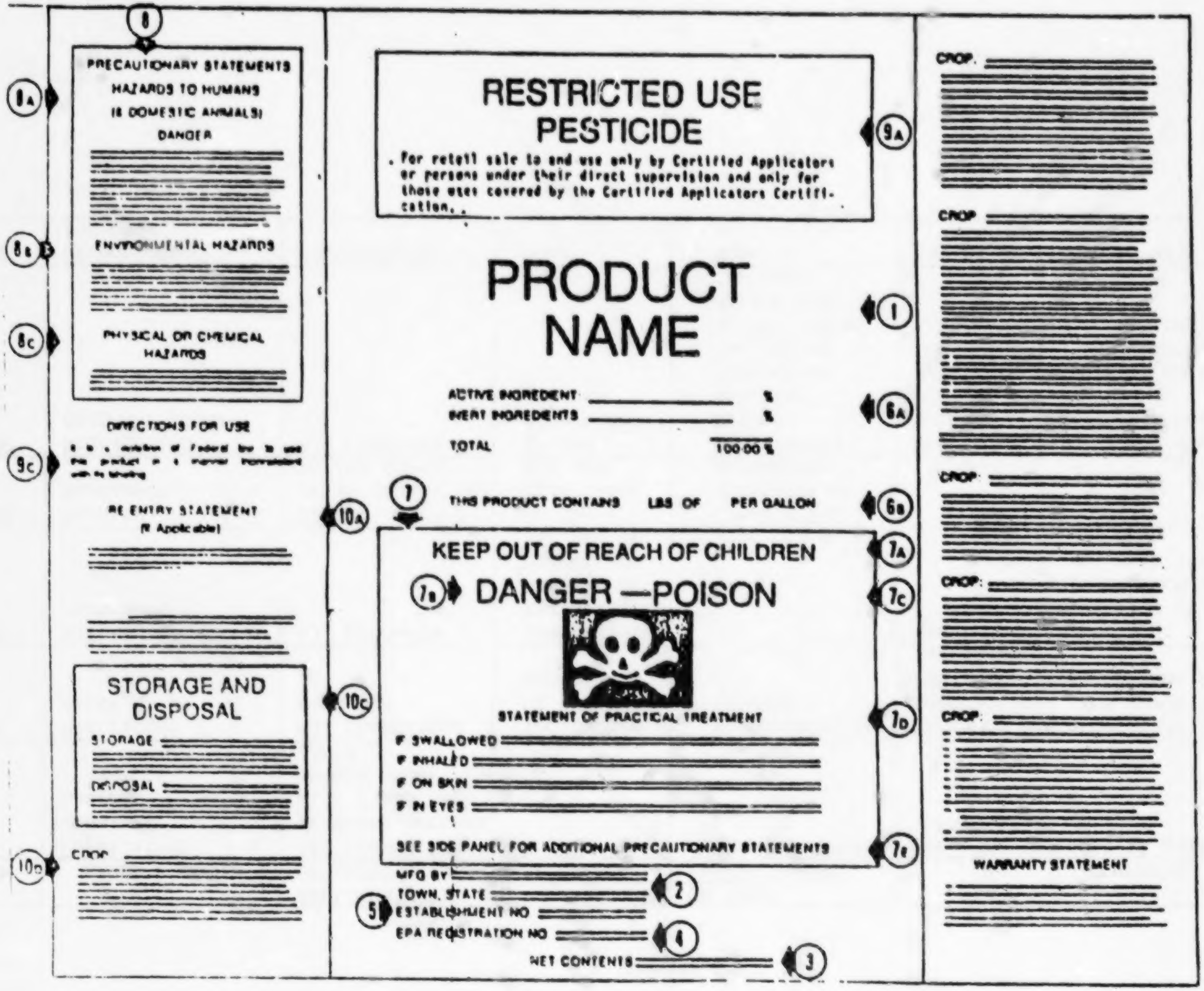
SUMMARY-6

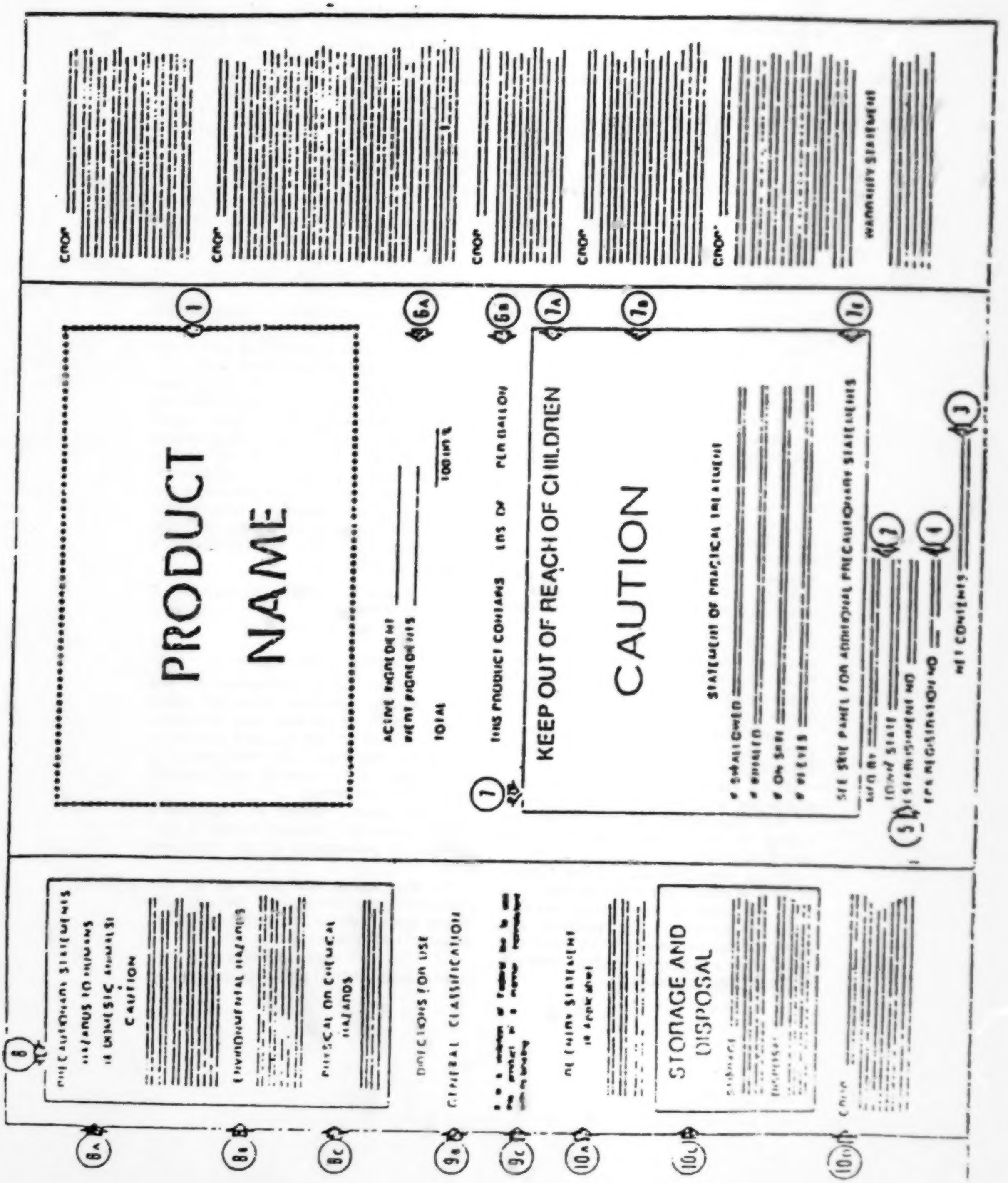
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units


8
8A
8B
8C
9C
10D
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
RE ENTRY STATEMENT
(If Applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP
10A
10C
7
RESTRICTED USE PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.
9A
PRODUCT NAME
1
ACTIVE INGREDIENT %
INERT INGREDIENTS %
TOTAL 100.00 %
6A
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
7B
DANGER —POISON
7C
STATEMENT OF PRACTICAL TREATMENT
7D
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP:
CROP
CROP:
CROP:
CROP:
WARRANTY STATEMENT


PRODUCT NAME
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00%
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
GENERAL CLASSIFICATION
RE-ENTRY STATEMENT
(IF APPLICABLE)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT
1
2
3
4
5
6A
6B
7
7A
7B
7C
8
8A
8B
8C
9A
9C
10A
10C
10D

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%.' If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC$_{50}$	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD$_{50}$	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practi-

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cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of

100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty~~

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE

TABLE OF CONTENTS

Site Name — Page

Agricultural Crops 2
Avocado 2
Blueberry 3
Cherry 4
Citrus Fruits 2
Citrus Fruits (nonbearing) 5
Corn (grown for decorative purposes) 8
Corn (including field, sweet, and popcorn) 6
Crucifers (grown for seed) 7
Deciduous Fruit Trees (nonbearing) 5
Dichondra 9
Ginseng 7
Ornamental Flowering Plants 9
Ornamental Ground Cover 9
Ornamental Lawns and Turf 9
Ornamental Plants 10
Ornamental Plants 11
Ornamental Plants (tropical ornamentals, nursery stock) 10
Ornamental and/or Shade Trees 9
Ornamental and/or Shade Trees (seed treatment for nursery stock) 10
Ornamental Woody Shrubs 9
Ornamental Woody Shrubs and Vines 9
Peppers (grown for seed) 7
Sunflower (grown for seed) 8

c100501 4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE*

TYPE PESTICIDE: Insecticide, Acaricide, Molluscicide, Repellent

FORMULATIONS:
Tech (99%)
FI (75%)
D (18.75%, 50%)
G (1%, 2%)
P/T (2%)
WP (75%)

GENERAL WARNINGS AND LIMITATIONS: All outdoor uses of methiocarb (except homeowner uses) are classified as RESTRICTED USE PESTICIDES. Certain 50 percent dust formulations are RESTRICTED USE PESTICIDES.** A 75 percent wettable powder formulation (Registration number 003125-00288) is only for agricultural use, or for sale to, use, and storage by commercial applicators, and other service persons. Do not use the 2 percent granular or pelleted/tableted formulations on or around plants grown for food. Do not apply the 75 percent wettable powder formulation with oil.
For the dusts and wettable powder formulations, wear protective clothing, natural rubber gloves, goggles, and a suitable mask or respirator. Do not enter treated fields for 24 hours following treatment. Consult a State Agricultural Extension Service regarding protective information.
Observe all warnings and limitations for the other active ingredient on the multiple active ingredient label and the SLNs.
Dosages are given in active ingredient.
Bee Caution: Methiocarb is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply methiocarb or allow it to drift to blooming crops on weeds if bees are visiting the treatment area.
Agricultural Crop Tolerances (other than those listed in the text):
Peaches - 15 ppm
Definition of Terms:
MAI - Multiple active ingredient(s)
SLN - Special Local Needs [24(C)]
**Refer to Auxiliary Documentation.

*methiocarb (BSI)
3,5-dimethyl-4-(methylthio)phenol methylcarbamate
Mesurol

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/28037AA	Agricultural Crops		No tolerance established. SLN: 14 day preplant interval through 0.8 pound per acre.
IGDAACA IGDAABA	Slugs Snails	[SLN] up to 0.8 lb/A (2% G)	SLN - Use limited to OR. Preplant soil application. Apply bait uniformly over areas to be treated by ground equipment or aircraft. Repeat as needed up to 14 days prior to planting.
/06001AA /02000AA	Avocado Citrus Fruits		0.02 ppm (citrus fruits) No tolerance established (avocado). SLN: No preharvest interval through 0.94 pound per acre for soil application. Do not make more than 2 applications per season. Do not allow formulation to come in contact with edible portions of plants.
IGDAABA	Snails	[SLN] up to 0.94 lb/A (2% G) (2% P/T)	SLN - Use limited to CA. Soil application. Apply by ground equipment between rows. Apply when needed and repeat 6 weeks later.
		[SLN] [MAI] 0.38-0.5 lb/A (1% G)	SLN - Use limited to CA. Soil application. Apply by ground equipment between rows. Apply when foliage and fruit is relatively dry but soil is wet following irrigation. Formulated with metaldehyde.

Also see Citrus Fruits (nonbearing) cluster.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01009AA	Blueberry		5 ppm (interim) 7 day preharvest interval through 3.0 pounds per acre per season for foliar application. SLN: No preharvest interval through 6.0 pounds per acre per season for foliar application.
VIVZPQA	Baltimore oriole	1.5 lb/A (75% WP) 003125-00288	Use limited to areas other than CA. Use expires March 31, 1988. Foliar application. Repellent. Apply by ground equipment or aircraft in a minimum of 5 gallons per acre. Apply as berries begin to ripen and repeat as needed to maintain repellency with at least 7 days between applications.
VIVFBAA	Blue jays		
VIVRBBA	Cedar wax wing		
VIWBAAA	Finches		
VIVZAOA	Grackles		
VIVZBEA	Red winged black bird		
VIVOBBA	Robin		
VIVUAAA	Starlings		
		[SLN] 1.5-2.0 lb/A (75% WP)	SLN - Use limited to AR, IN, NH, NY, OR, PA, VT, and WA.
IOBMAPA	Blueberry maggot (adult)	0.75-1.3 lb/A (75% WP)	Use limited to areas other than CA. Use expires March 31, 1988. Foliar application. Apply by ground equipment or aircraft in a minimum of 5 gallons per acre. Apply in accordance with local conditions using the higher rate when population densities are high. Repeat at minimum 7 day intervals as needed.
		*[SLN] 0.75-1.5 lb/A (75% WP)	SLN - Use limited to AR, IN, NH, NY, PA, and VT.

*Refer to Auxiliary Documentation.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
705002AA	Cherry		5 ppm (interim) 14 day preharvest interval through 3.0 pounds per acre per season for foliar application. 3 day preharvest interval through 1.5 pounds per acre for 1 foliar application per season. SLN: 7 day preharvest interval through 4.0 pounds per acre for foliar application. Do not make more than 3 applications per season. Do not graze or feed cover crops grown in treated areas.
VIVFBAA	Blue jays	1.5 lb/A or 0.5 lb/100 gal (75% WP) 003125-00288	Use limited to areas other than CA. Use expires March 31, 1988. Foliar application. Apply by ground equipment in 300 gallons per acre or by aircraft in a minimum of 5 gallons per acre. Apply as cherries begin to ripen and repeat as needed with a minimum of 7 days between applications.
VIVRBBA	Cedar wax wing		
VIWBAAA	Finches		
VIVZADA	Grackles		
VIVOBBA	Robin		
VIWBAAA	Sparrows		
VIVUAAA	Starlings		
		*[SLN] 2.0-4.0 lb/A (75% WP)	SLN - Use limited to CA, NY, UT, and WA. Foliar application. Repellent. Apply by ground equipment as full coverage spray or by aircraft in a minimum of 5 gallons per acre. Apply as cherries begin to ripen. Use the higher rate for larger or denser trees or both.
IOBMALA	Cherry fruit fly	0.75-1.0 lb/A or 0.25-0.33 lb/ 100 gal (75% WP)	Use limited to areas other than CA. Use expires March 31, 1988. Foliar application. Apply by ground equipment in 300 gallons per acre or by aircraft in a minimum of 5 gallons per acre. Apply as needed with a minimum of 7 days between applications.
ILAVASA	European red mite		
ILAVAYA	McDaniel spider mite		
INASAVA	Plum curculio		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cherry (continued)		
		*[SLN] 0.75-1.0 lb/ 100 gal [max. 400 gal/A] (75% WP)	SLN - Use limited to NY. Foliar application. Apply the high rate as an eradicative treatment for heavy pest populations and for plum curculio. Apply the low rate in seasonal spray programs. Repeat as needed. For cherry fruit fly and plum curculio, consult a State Agricultural Extension Service regarding the number and timing of sprays in seasonal spray programs.
		*Refer to Auxiliary Documentation.	
/02000DA /28038DA	Citrus Fruits (nonbearing) Deciduous Fruit Trees (nonbearing)		0.02 ppm (citrus fruits) No tolerance established (deciduous fruit trees). Apply through 6.0 pounds per acre per season for foliar application. Do not make more than 4 applications per season. Do not apply to trees that will bear fruit within 1 year of application.
IRACAAA ILAAABA	Aphids Mites	0.375-0.75 lb/50 gal/A (75% WP) 003125-00288	Foliar application. Apply spray until thoroughly wet. Repeat as needed.
IGDAACA IGDAABA	Slugs Snails	1.5 lb/50 gal/A (75% WP)	
			Also see Avocado cluster.

4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
728005AA	Corn (including field, sweet, and popcorn)		0.03 ppm (fresh [including sweet (K+CWHR)]) (fodder) (forage) (grain, field) (grain, pop) 120 day (50 percent dust) or 80 day (75 percent wettable powder) preharvest interval through 0.1 pound per 20 pounds cracked corn per acre for bait application. Apply 1 bait application per season. Seed treatment through 0.5 pound per 100 pounds of seed. Treated seeds must not be left exposed on soil surface or be used for food, feed or oil purposes. The formulations may be phytotoxic to corn under cool, wet growing conditions. For seed treatment and bait application, refer to appropriate labeling for Endangered Species Restrictions.
VIVZABA VKGHBDA VIHEBHA VKGGDGA	Blackbirds Mice [SLN] Pheasant Prairie vole	0.25-0.5 lb/ 100 lb seed or 1.5-4.5 oz/bu (18.75%, 50% D) 003125-00309 or *1.125-6.0 oz/100 lb seed (75% WP) 007501-00088	*RESTRICTED USE PESTICIDE (50 percent dust). Seed treatment. Repellent. Apply the dusts to seed in the hopper or a container. Apply the high rate for pheasants or prairie voles. Apply the wettable powder as a slurry using 1.125 to 2.25 ounces per hundred pounds seed for blackbirds and 3.0 to 6.0 ounces for pheasants and prairie voles.
IGDAACA IGDAABA	Slugs Snails	[SLN] 0.1 lb/20 lb cracked corn/A (50% D) (75% WP)	SLN - Use limited to DE, IN, MD, MI, NY, OH, PA, VA, and WV. Bait application. Apply as a broadcast application to the soil surface when snail or slug damage becomes apparent. The cracked corn may be moistened for application of the wettable powder.

*Refer to Auxiliary Documentation

4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28053BA	Crucifers (grown for seed)		No tolerance established. SLN: 7 day preharvest interval through 2.0 pounds per acre for foliar application. Do not make more than 2 applications. Do not use foliage as feed for livestock. Seeds from treated plants must not be consumed by humans or animals.
VIAAAAA	Birds	[SLN] 2.0 lb/A (75% WP)	SLN - Use limited to CA. Foliar application. Repellent. Apply a maximum of 2 postbloom sprays in 35 to 50 gallons by ground equipment or in 10 gallons by aircraft.
/26013AA	Ginseng		N.F. 12 month preharvest interval through 0.32 ounce per 1,000 square feet.
IGDAACA	Slugs	[SLN] 0.32 oz/1,000 sq.ft (2% P/T) NC860003 WI860002	SLN - Use limited to NC and WI. Broadcast soil application. Apply by hand held equipment or powered ground equipment. Begin applications in the spring when the mulch layer is moist and repeat in 6 week intervals as needed.
/28017BA	Peppers (grown for seed)		No tolerance established. SLN: 7 day preharvest interval through 4.0 pounds per acre for foliar application. Do not apply more than 2 sprays per year. Do not use peppers as feed for humans or livestock.
VIAAAAA	Birds	[SLN] 2.0-4.0 lb/A (75% WP)	SLN - Use limited to Ventura County, CA. Foliar application. Repellent. Make 2 applications by aircraft in a minimum of 10 gallons per acre.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28012BA	Sunflower (grown for seed)		No tolerance established. SLN: 7 day preharvest interval through 4.0 pounds per acre for foliar application. Do not make more than 3 applications per year. Do not use as feed for humans or livestock.
VIVZABA	Blackbirds	[SLN] up to 4.0 lb/A (75% WP)	SLN - Use limited to Glenn County, CA. Foliar application. Repellent. Make 3 applications by aircraft in a minimum of 10 gallons per acre.

TERRESTRIAL NONFOOD CROP

(Ornamental Plants and Forest Trees)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28005AA	Corn (grown for decorative purposes)		Do not use as feed for humans or livestock.
VIAAAAA ILAVBEA	Birds Twospottted spider mite	[SLN] up to 3.0 lb/A (75% WP)	SLN - Use limited to San Benito and Santa Clara Counties, CA. Foliar application. Make 3 applications per year in a minimum of 100 gallons per acre by ground equipment or 10 gallons per acre by aircraft.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/33028AA /31003AA /33009AA /33008AA /34000AA	Dichondra Ornamental Flowering Plants Ornamental Ground Cover Ornamental Lawns and Turf Ornamental Woody Shrubs and Vines		Do not use on or around plants grown for food. Apply in flower beds, gardens, planted borders, greenhouses, under greenhouse benches, and around building foundations. For ornamental lawns and turf (golf courses and sod farms), refer to appropriate labeling for Endangered Species Restrictions.
IVAHAAA IJCAAAA IGDAACA IGDAABA IIFAAEA	*(Crickets) *(Millipedes) Slugs Snails Sowbugs	0.02 lb/1,000 sq.ft (2% G) 003125-00234 (2% P/T) 000239-02534	Soil or foliar application. Apply to soil around plants or broadcast over foliage.* Repeat as needed. Water area before applying bait. Apply uniformly so that bait is hardly visible on the ground. Do not apply in piles. Withhold heavy watering for at least 2 days after treatment. For dichondra and grass, sprinkle lightly to wash granules or pellets off foliage to soil.
		[SLN] [MAI] 0.01 lb/1,000 sq.ft (1% G)	SLN - Use limited to CA. Formulated with metaldehyde.
		*Refer to Auxiliary Documentation.	
/31003AA /35000AA /34004AA /32000CA	Ornamental Flowering Plants Ornamental and/or Shade Trees Ornamental Woody Shrubs		Do not apply in conjunction with foliar fertilizer applications.
IRACAAA ILAAABA	Aphids Mites	0.375-0.75 lb/50 gal/A (75% WP) 003125-00288	Foliar application. Apply until thoroughly wet. Repeat as needed up to 4 times per season.
IGDAACA IGDAABA	Slugs Snails	1.5 lb/50 gal/A (75% WP)	

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/32000AA /32000CA	Ornamental Plants		
IGDAACA	Slugs	[SLN] 0.975 lb/100 gal (75% WP)	SLN - Use limited to OR. Use limited to commercial growers or professional applicators only. Foliar application. Apply as a full coverage spray. Repeat as needed. Under greenhouse conditions treat only a few plants and observe for varietal sensitivity before treating the entire planting.
IGDAABA	Snails	[SLN] 1.5 lb/100 gal (75% WP)	
/32000DA	Ornamental Plants (tropical ornamentals, nursery stock)		
IGDAABA	Snails	[SLN] 0.825 oz/ 1,000 sq.ft (75% WP)	SLN - Use limited to CA. Foliar application. Apply as needed by ground equipment in not less than 20 gallons. Water must not exceed a pH of 6.8.
/35000DA	Ornamental and/or Shade Trees (seed treatment for nursery stock)		Do not use treated seed for food or feed.
VIVZBKA	Cowbirds	[SLN] 8.0 oz/100 lb seed (75% WP)	SLN - Use limited to ME and NH. Seed treatment. Repellent. Apply using equipment capable of uniformly mixing formulation and seed. The addition of a sticking agent (maximum 1 pint per 100 pounds of seed) such as milk, cola, or vegetable oil will enhance adherence to the seed.
VIVFABA	Crows		
VIVZADA	Grackles		
VIMBBDA	Mourning doves		
VIWBAAA	Sparrows		

GREENHOUSE NONFOOD CROP

(Ornamental Plants and Forest Trees)

/32000CA Ornamental Plants

Refer to TERRESTRIAL NONFOOD CROP, (Ornamental Plants and Forest Trees), Dichondra cluster, Ornamental Flowering Plants cluster, and Ornamental Plants, for use and limitation information.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

DOMESTIC OUTDOOR

(Ornamental Plants and Forest Trees)

Ornamental Plants

Refer to TERRESTRIAL NONFOOD CROP, (Ornamental Plants and Forest Trees), Dichondra cluster, Ornamental Flowering Plants cluster, and Ornamental Plants, for use and limitation information.

AERIAL AND TANK MIX APPLICATIONS

9001500
AAAAAAA Aerial Application

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Refer to
TERRESTRIAL FOOD CROP
(Agricultural Crops)
Agricultural Crops [SLN], Blueberry, Cherry, Crucifers (grown for seed) [SLN], Peppers (grown for seed) [SLN], Sunflower (grown for seed) [SLN]
TERRESTRIAL NONFOOD CROP
(Ornamental Plants and Forest Trees)
Corn (grown for decorative purposes) [SLN]

4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE

Listing of Registered Pesticide Products by Formulation

&099.0001 99% technical chemical
4-(methylthio)-3,5-xylyl methylcarbamate (100501)
003125-00258

&075.0002 75% formulation intermediate
4-(methylthio)-3,5-xylyl methylcarbamate (100501)
003125-00257

&016.7503 16.75% dust
4-(methylthio)-3,5-xylyl methylcarbamate (100501)
007832-00004*
*jacket currently unavailable for review

(007832-00004) AR780031 NY790001

&050.0003 50% dust
4-(methylthio)-3,5-xylyl methylcarbamate (100501)
000004-00254 002393-00337 003125-00309 007501-00089

(003125-00309) AR770001 IL790005 IN810019 IN830004
KY810001 MI830018 MO770001 OH820017
UT820010 WA790007

&001.0004 1% granular
4-(methylthio)-3,5-xylyl methylcarbamate (100501) plus metaldehyde (053001)
005481-00195*
*jacket currently unavailable for review

&002.0004 2% granular
4-(methylthio)-3,5-xylyl methylcarbamate (100501)
000004-00242 000070-00247 000239-02416* 003125-00234
004887-00176 005481-00189 005967-00068 006720-00222
007001-00283 007401-00342
*jacket currently unavailable for review

CA780146

(003125-00234) OR820067

(007001-00283) CA780040

&002.0005 2% pelleted/tableted
4-(methylthio)-3,5-xylyl methylcarbamate (100501)
000239-02534 000572-00281 000769-00449 000802-00500
001386-00576 002393-00241 006720-00220

CA780116

Listing of Registered Pesticide Products by Formulation (continued)

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&075.0006 75% wettable powder
   4-(methylthio)-3,5-xylyl methylcarbamate (100501)
     003125-00266   007501-00086

     (003125-00288)        AR810022  CA770034  CA770311  CA790161
                           CA820010  CA840199  CT810001* DE840004
                           IN810020  IN840007  ME840002  MD810016*
                           MD840002  MI790010* MI840010  NH810003
                           NH840003  NY770003  NY780025  NY810021
                           NY840002  OH840002  OR800067  OR810036
                           PA810016  PA840007  UT790001  VA840003
                           VT810002  WA770015  WA790017* WA800064
                           WV840002
        *jacket currently unavailable for review
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9999999   State Label Registrations

     CA Reg. No.
       005481-03857   006973-03601   011656-05774

     FL Reg. No.
       000557-06950

     PR Reg. No.
       034120-09500
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EPA Index to Pesticide Chemicals

4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
053001	--	metaldehyde

-- use Common Name

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4-(METHYLTHIO)-3,5-XYLYL METHYLCARBAMATE

Auxiliary Documentation

Registration numbers 002393-00337 (50% D, 6/7/76 stamp) and 000004-00254 (50% D, 2/2/76 stamp) have Restricted Use Pesticide on the label. The other 50% D labels, 003125-00309 (stamp 1/12/83) and 007501-00089 (stamp 7/17/86), and the 18.75% D (stamp 6/30/83) do not have this restriction.

The fiche copy (dated 6/30/83) for 007832-00004 (18.75% D) was used for the report.

The following SLN registrations have been withdrawn or cancelled by California:

CA770161	cancelled 2/22/78
CA790064	cancelled 6/29/78
CA780119	cancelled 6/29/83
CA780120	cancelled 8/29/83
CA780158	cancelled 6/29/83
CA790031	withdrawn 2/29/84

The dosage rates from 003125-00288 on blueberry and cherry have been reduced to bring residues down to 5 ppm (from the old tolerance of 25 ppm). However, the SLN labels have not followed suit and still bear the old application rate, which by Mobay's own admission, will result in residues in excess of 5 ppm.

Regarding the corn seed treatment use from 007501-00088 (75% WP): A letter of conditional registration (dated 7/8/86) from the Agency to the registrant states that the dose for pheasant and vole repellancy should be 10.5 ounces a.i./cwt seed unless the dose of 3.0-6.0 a.i. ounces given on the label can be justified.

Registration number 007401-00342 (2% G) gives control for all pests including crickets and millipedes. Other labels have the use as an "aid to control" millipedes or crickets.

Of all slug and snail bait uses, only 003125-00234 (2% G) gives directions for broadcast over foliage. All other labels give "Do not apply to foliage" directions.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00035520	Strankowski, K.J.; Stanley, C.W. (1978) Determination of Residues of Mesurol and Its Toxic Metabolites in Crops: Report No. 45089. (Unpublished study including report nos. 53015, 53701 and 62625, received Jun 19, 1980 under 0F2362; prepared in cooperation with International Research & Development Corp. and others, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:099475-B)
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00035523	Nichols, S.S. (1979) Addition to Synopsis of Mesurol: Residue Chemistry on Corn. (Unpublished study received Jun 19, 1980 under 0F2362; prepared in cooperation with Analytical BioChemistry Laboratories and others, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:099477-A)
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00036477	Crawford, C.R.; Anderson, R.H. (1973) The Acute Oral Toxicity of Mesurol Technical to Rats: Report No. 34008. Rev. (Unpublished study received Mar 26, 1975 under 5F1607; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094391-T)
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00037132	Chemagro Corporation (1971) Synopsis of Mesurol: Analytical and Residue Information for Seed Treatment of Corn: (Unpublished study received Jul 2, 1975 under 6F1652; CDL:094636-A)
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00124968	Abdel-Wahab, A.; Kuhr, R.; Casida, J. (1966) Fate of C14-carbonyl-labeled aryl methylcarbamate insecticide chemicals in and on bean plants. J. Agr. Food Chem. 14(3):290-297. (Submitter 18274; also In unpublished submission received Jul 15, 1976 under 3125-EX-135; submitted by Mobay Chemical Corp., Kansas City, MO; CDL:227756-E)
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MRID	CITATION
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*U.S. GOVERNMENT PRINTING OFFICE: 1987-716-002/60600

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. **My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:**

3. **My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):**

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. **My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.**

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT-SPECIFIC DATA REPORT

EPA Reg. No.__________________________ Date ____________________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ____________ concerning a requirement for submission of "generic" data on the active ingredient ______________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________________ and their registration number(s) is/are ______________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: ____________________ ______________________________
(Typed)